

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS
(Phentermine/Fenfluramine/Dexfenfluramine)
PRODUCTS LIABILITY LITIGATION

MDL Docket No. 1203

This Document Relates to:
SHEILA BROWN, et al., v. AMERICAN HOME
PRODUCTS CORPORATION

Civil Action No. 99-20593

Pretrial Order No. 3882
(Resumption of the Parallel Processing Program)

AND NOW, this 26th day of August, 2004, it is hereby ORDERED,
ADJUDGED and DECREED that:

- (1) Wyeth and Class Counsel are authorized to resume the Parallel Processing Program for High Level Claims in accordance with the Procedures described in Exhibit "A" to this Order; and
- (2) The Trust is authorized and directed to process High Level Claims in accordance with the terms of the Procedures appended hereto as Exhibit "A" and is further directed to cooperate with Wyeth and Class Counsel in processing and paying High Level Claims in accordance with those procedures;
- (3) The Court, for good cause shown, may modify the procedures for parallel processing of high level claims (except for ¶ 16).

BY THE COURT:


HARVEY BARFLE, III, J.

PARALLEL PROCESSING OF HIGH LEVEL CLAIMS

Citations are to the Nationwide Class Action Settlement Agreement, as Amended. Capitalized terms not otherwise defined in these Procedures have the meanings given them in that Agreement.

1. **Scope.** These Parallel Processing Procedures (“Procedures”) apply to: (a) all claims for Matrix Compensation Benefits where the answers to Part II of the Green Form support a claim with a Matrix Level of Severity of III, IV and/or V, under Section IV.B.2.c(3)-(5) [pp.42-48] of the Settlement Agreement; and (b) all Supplemental Claims for Matrix Compensation Benefits on Matrix Level III, IV and/or V under Section IV.C.3 [p.54] of the Settlement Agreement, which the Trust:

- (a) Has not sent to Audit; or
- (b) Has sent to Audit but has not entered Auditing Cardiologist findings in its database; or
- (c) Has sent to Audit and has issued a Medical Status Letter or additional correspondence relating to a Medical Status Letter as the last correspondence on the claim.

These claims are collectively referred to in these Procedures as “High Level Claims.” These Procedures also apply to the Additional Cash or Medical Services claims under Section IV.A.1.c [pp. 32-33] of the Settlement Agreement that are associated with the High Level Claims processed under these Procedures.

2. **Applicability to Seventh Amendment Matrix Compensation Benefits.** If the Seventh Amendment to the Settlement Agreement attains Final Judicial Approval, these Procedures shall apply to claims for Seventh Amendment Matrix Compensation Benefits, as defined in the Seventh Amendment, which shall also be referred to in these Procedures as High Level Claims.

3. **Parties Implementing these Procedures.** Class Counsel shall designate one person to represent Class Counsel, and Wyeth shall designate one person to represent Wyeth in connection with these Procedures. Such persons shall serve as the PPP Committee. The PPP Committee shall designate such other support persons as are necessary to carry out these Procedures. Members of the SALC, as defined in the Seventh Amendment, may assist Class Counsel and the PPP Committee with the implementation of these Procedures. Any person assisting Class Counsel shall have access to all information concerning the Parallel Process and claims processed by the Parallel

Process on a confidential basis as Authorized Persons pursuant to PTO 2683, including the limitation in Paragraph 5(d) of that Order. In connection with implementing these Procedures, the parties agree to proceed in good faith in the evaluation of the medical proof and determination of a Class Member's actual medical condition.

4. ***Intake and Initial Processing of High Level Claims.*** The AHP Settlement Trust ("Trust") shall perform the necessary tasks associated with the receipt, scanning, and data input into the Trust's claims database of all materials received by the Trust relating to High Level Claims.

5. ***Contact with Class Members.*** When these Procedures refer to any contact with Class Members, the contact shall be with counsel for Class Members shown as represented by counsel in the Trust's claims database, and directly with Class Members shown as unrepresented in the Trust's claims database.

6. ***Initiation of the Process.***

(a) ***Identification of Claimants Asserting a High Level Claim.*** The Trust shall keep its database current on all claims processing steps taken, information received, and the current status of any High Level Claim. No later than 15 days after Trial Court Approval of these Procedures, the Trust shall identify each High Level Claim on file with the Trust and shall provide to the PPP Committee a report, in electronic form, listing the DDR, claimant name, Matrix Level of Severity supported by the answers in Part II of the Green Form, and the following information about the status of each such High Level claim:

- (1) Whether it has been paid and, if so, the date and amount of payment;
- (2) What determination letters, if any, have been sent to the claimant, and the dates of any such letter;
- (3) Whether the Trust considers the claim to be complete;
- (4) If the Trust considers the claim to be incomplete, identification of any missing information, the deficiency notices sent by the Trust on such claims, and the responses to such notices.

The Trust shall continue to provide this report and all information required in this Section 6(a) to the PPP Committee no later than 15 days of its receipt of any High Level Claim. The PPP Committee shall have the right to identify additional claims that, upon information and belief, are High Level Claims, and such claims shall be processed in accordance with these Procedures.

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- (b) ***Access to Claims and Information at the Trust.*** The PPP Committee shall have complete access to all hard copy and electronic documents, echocardiogram tapes/disks, and other information in the possession, custody, and control of the Trust for all High Level Claims. The PPP Committee shall also have complete access to any spreadsheet or other database the Trust uses to record and track the receipt and location of all echocardiogram tapes and disks maintained by the Trust. In addition, the Class Counsel Claims Office shall have complete access to the Trust's claims database for all High Level Claims. The Trust shall provide Wyeth access to echocardiogram tapes/disks for copying on site at the Trust. If it is not possible to copy echocardiogram tapes/disks on site at the Trust, such disks may be copied off site, provided that procedures are established to ensure that a proper and documented chain of custody is followed.
- (c) ***Class Counsel's Submission of Echocardiogram Tapes to the Trust.*** Where Class Counsel receives a copy of an echocardiogram tape or disk directly from the claimant, Class Counsel shall send the tape or disk to the Trust. This transmission will be accompanied by a list that contains the names and DDR numbers of the claimants for whom tapes are being transmitted at that time. Class Counsel shall provide Wyeth with a copy of that list. The Trust shall enter the echocardiogram into the spreadsheet or database module it uses to track the receipt and location of all echocardiogram tapes and disks received and maintained by the Trust.

7. ***Use of Transesophageal Echocardiograms and Cardiac Catheterizations to Support High Level Claims.***

- (a) Where Records Indicate Existence of a Transthoracic Echocardiogram. If the claimant has submitted either a transesophageal echocardiogram or cardiac catheterization in support of a claim, but the medical records indicate that a transthoracic echocardiogram exists, Class Counsel shall attempt to obtain a copy of the transthoracic echocardiogram for inclusion in the claim materials to be transferred to Wyeth under Section 9 of these Procedures.
- (b) Transesophageal Echocardiograms. With respect to all High Level Claims, a transesophageal echocardiogram that provides satisfactory clinical evidence of the disease conditions that would otherwise support a claim shall be sufficient to complete a claim for determination of eligibility for Matrix Compensation Benefits and Additional Cash or Medical Services.

- (c) Cardiac Catheterizations. With respect to all High Level Claims based on surgery to repair or replace the aortic and/or mitral valve, a cardiac catheterization that provides satisfactory clinical evidence of FDA Positive regurgitation, or Mild Mitral regurgitation for claims based on Mild Mitral regurgitation and surgery, shall be sufficient to complete a claim for determination of eligibility for Matrix Compensation Benefits and Additional Cash or Medical Services.

8. *Determination of the Completeness of Each Claim.*

- (a) Completeness Review. No later than 90 days after the PPP Committee's receipt of the list and report in Section 6(a) of these Procedures, Class Counsel shall review each claim to determine if it is sufficiently complete within the meaning of Section VI.C.2 [pp.90-94] and Section VI.C.4 [pp.103-111] of the Settlement Agreement to permit making a determination of eligibility for Matrix Compensation Benefits as a High Level Claim. Missing information shall be considered a deficiency that renders a claim incomplete only if material to making that determination. No claim submitted for Matrix A benefits will be sent to Wyeth under Section 9 of these Procedures unless and until the Class Member has complied with Court Approved Procedure No. 4 as approved by PTO No. 2805.
- (b) Steps to Be Taken by Class Counsel to Complete Files. No later than 15 days after the determination of the deficiencies that are material to the completeness of claim, Class Counsel shall notify the Class Member in writing of all such deficiencies and shall provide each Class Member with three 30-day opportunities to supply the information. Class Counsel shall have the discretion to contact Class Members and subrogees by telephone as part of the deficiency process. Class Counsel shall document all telephone contact and identify the date and time of the call, as well as its content. If the claim remains incomplete after the conclusion of the third opportunity and the Class Member has informed Class Counsel of efforts taken to obtain the required information, Class Counsel shall continue to work with the Class Member to obtain the information until such time as Class Counsel determines that the information cannot be obtained and that it should not process the claim further. Upon Class Counsel's determination that the information cannot be obtained, or if the claim remains incomplete after the conclusion of the third opportunity and the Class Member has not notified Class Counsel of any attempt to obtain the information, Class Counsel shall not process the claim further and shall return the claim and its records of all written and oral contacts with the Class Member to the Trust. The Trust shall

close the claim and not process it further, unless the Class Member establishes to the Trust good cause to reopen the claim.

- (c) **Retention of Information Obtained.** Class Counsel shall provide a copy of all information obtained from the Claimant to Wyeth as provided in Section 8 of these Procedures, and to the Trust. The Trust shall scan the information into the Class Member's file in its claims database.
- (d) **Information Regarding Potential Subrogees:**
 - (1) **For High Level Claims that are not claims for Seventh Amendment Matrix Compensation Benefits:**
 - a. Where the subrogation block on the Claim Form (GREEN Form, Part III, Question 5) is checked "Yes," Class Counsel will ensure that all necessary information appears on the Claim Form to enable the Trust to identify the potential subrogee. If the Class Member is unrepresented, Class Counsel will confirm all information contained in this question and will forward this information to the Trust.
 - b. Where the subrogation block on the Claim Form (GREEN Form, Part III, Question 5) is not checked, Class Counsel will contact the Class Member's attorney to determine the appropriate response and receive written confirmation from the Class Member's attorney. If the Class Member is unrepresented, Class Counsel will contact the Class Member, determine the appropriate response, obtain the information contained in this question and will forward that information to the Trust.
 - c. Where the subrogation block on the Claim Form (GREEN Form, Part III, Question 5) is checked "No," the Trust will address the subrogation issue in the tentative Matrix Benefits determination letter and in a legend on any check to the Class Member.

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- (2) When processing Seventh Amendment Matrix Compensation Benefits, Class Counsel shall take all steps necessary to obtain Class Member's compliance with the requirements of Section XV.W. of the Seventh Amendment, and the Trust shall process all Seventh Amendment Matrix Compensation Benefits in accordance with that Section.

9. *Transmittal of Complete Claims to Wyeth.*

- (a) Transfer of List of Completed Claims to Wyeth and the Trust. By noon each Wednesday, Class Counsel shall provide Wyeth with a list of the High Level Claims it determined to be sufficiently complete to make a High Level Claim determination during the preceding week ("the List"), as well as any documents newly-received from the Class Member for any claim appearing on the List. Class Counsel shall indicate its determination of duration of drug use and shall specify the value of claim.
- (b) Incomplete Designations by Wyeth. No later than 20 days after its receipt of the List, if Wyeth considers the claim incomplete, Wyeth shall notify Class Counsel and the Trust of the information needed. During this 20 day period, Wyeth and Class Counsel will confer to determine if the claim is complete. If Class Counsel agrees that the claim is incomplete, Class Counsel will take steps to obtain such information from the Class Member. If Wyeth and Class Counsel cannot agree on whether the claim is incomplete, the claim shall be referred to the Special Master (Gregory Miller) for a determination of whether the claim is complete.

10. *Claims Determinations.* After its review of the claim forms and Medical Information (including echocardiogram tape or disks or other applicable proof), and no later than 30 days after its determination that the claim is complete (i.e., agreed as complete by Wyeth, agreed as complete between Wyeth and Class Counsel, or ruled as complete by the Special Master), Wyeth will notify the Trust and Class Counsel as to each claim that the Matrix claim and/or its associated Additional Cash and Medical Services claim is designated by Wyeth as:

- (a) Payable; or,
- (b) Payability Disputed.

11. *Wyeth's Actions on Designated Claims.*

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- (a) **Payable Designations.** With respect to each claim designated by Wyeth as Payable, Wyeth shall notify the Trust and Class Counsel of the benefit level and amount of the claim, based on the documentation and information reviewed by Wyeth.
- (b) **Payability Disputed Designations.** With respect to each claim designated by Wyeth as Payability Disputed, Wyeth shall notify the Trust and Class Counsel of the reasons why payability is disputed.
 - (1) **Deficient Proof.** If Wyeth disputes the payability of a claim because of a non-evaluable echocardiogram tape (in whole or in part, where the non-evaluable echocardiogram tape prohibits an evaluation of the factor necessary to support the claim) Wyeth shall specify these reasons in its designation, and Class Counsel shall seek to cure those deficiencies as provided in Section 8(b) of these Procedures. If Class Counsel obtains a better copy of the tape, Class Counsel shall send it to the Trust and to Wyeth, and the processing of the claim will commence anew pursuant to Section 9(a) of these Procedures and will continue in accordance with all subsequent Sections. If Class Counsel is not able to obtain a better copy of the tape, Class Counsel shall notify the Trust and Wyeth, and the claim shall be processed as a Medical Disagreement pursuant to Section 11(b)(2) of these Procedures.
 - (2) **Medical Disagreement.** If Wyeth disputes the payability of a claim because it disagrees with the medical condition claimed on the Green Form, or disagrees with the evaluability of a tape as provided in Section 11(b)(1) of these Procedures, Wyeth shall specify which question(s) in Part II of the Green Form it disagrees with, and this question(s) will be the only question(s) submitted to the Auditing Cardiologist for review during Audit (the "Audit Question(s)").

12. The Trust's Actions on Designated Matrix Claims. After receipt of the response from Wyeth pursuant to Sections 10 and 11 above:

- (a) **Payable Claims:** With respect to each claim designated by Wyeth as payable, the Trust shall, as soon as possible, but no later than 30 days after the date of Wyeth's designation, perform a review of the claim to verify that the Class Member filed a Green Form and has the name and claim number of the claim included in Wyeth's designation. After this review and also within 30 days, the Trust shall issue a

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determination letter to the Class Member. This letter shall notify the claimant of the determination on the claim including the appropriate deductions for attorneys' fees and subrogation claims as required by Section VI.C.4.n [p. 111] of the Settlement Agreement and shall provide the claimant an opportunity to accept the amount without prejudice to contest the Matrix or severity level of the claim. The Trust shall not run the Green Form algorithm, require additional completeness steps, or conduct any additional review of the claim, but instead shall process the claim at the level and amount specified in Wyeth's designation. Once a month, the Trust shall aggregate all claims designated as Payable by Wyeth during the preceding month and shall file the list with the Court, accompanied by a Motion for an Order authorizing the Trust to pay the claim(s) in accordance with the amount determined by Wyeth. The Trust shall pay the claims within five days of the Court's entry of the Order authorizing payment.

To the extent that the claimant contests the Matrix or severity level of the claim, the claim will be deemed a Medical Disagreement under Section 11(b)(2) of these Procedures and shall be processed in accordance with Sections 11(b)(2), 12(b) and 13 of these Procedures.

- (b) Payability Disputed Claims. With respect to each claim designated by Wyeth as Payability Disputed on the basis of a medical disagreement under Section 11(b)(2), the Trust shall, no later than 15 days after its receipt of Wyeth's designations, transmit any claim with a Payability Disputed designation for medical disagreement under Section 11(b)(2) to an Auditing Cardiologist. The Trust shall not conduct a completeness review of the claim prior to sending it to Audit. The Auditing Cardiologist shall decide whether there was a reasonable medical basis for the Attesting Physicians' answers to only those Audit Question(s) identified by Wyeth in Section 11(b)(2) of these Procedures. The Trust's processing of claims in Audit shall be governed by the Audit Rules approved by the Court in Pretrial Order No. 2807, except for Rules 3, 4, 5, 7, 8, (and any related Definitions in Rule 1), which are superseded by these Procedures.

13. Contests Following Audit. If the claimant contests an Audit finding in accordance with Audit Rule 18(b), the Trust shall forward all materials submitted by the claimant in contest to Class Counsel and Wyeth no later than five days of the Trust's receipt of such materials. Wyeth shall review the contest materials and shall notify the Trust and Class Counsel, in writing, no later

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than ten days following its receipt of the contest materials, whether the claim is Payable or remains Payability Disputed. If the claim is Payable, Wyeth shall provide the Trust with the information specified in Section 11(a) of these Procedures, and the Trust shall issue a Final Post-Audit Determination, in accordance with Audit Rule 18(c), that the claim is Payable. If, after review of the contest materials, Wyeth maintains that the claim is not payable, Wyeth shall provide the Trust with the information specified in Section 11(b) of these Procedures, which the Trust shall consider when deciding whether to issue a Final Post-Audit Determination in accordance with Audit Rule 18(c), denying the claim.

14. *Derivative Claims.* The Trust shall process in accordance with Section IV.B.2 of the Settlement Agreement, as amended, all Derivative Claims associated with any claim of a Diet Drug Recipient included in this process.

15. *Processing of Undisputed Benefits.* If the Trust determines that there exists a question or issue that may result in the need for further processing or inquiry into the validity or amount of a Derivative Claim or in the need to make legal determinations about a Derivative Claim, the pendency of that processing, inquiry or need for determination shall not delay the processing or payment of a claim for Matrix Benefits that may be payable to a Diet Drug Recipient or his or her Representative Claimant.

16. *Suspension or Cancellation of this Procedure.* Wyeth and/or Class Counsel have the right to cancel this Procedure upon thirty days' written notice to the Trust's Executive Director (or other chief executive officer), as to all High Level Claims that remain unpaid after the effective date of such notice.

17. *Duration of this Procedure.* This procedure shall terminate upon the earlier of: (i) cancellation pursuant to Section 16 above; (ii) an order of the Trial Court directing relief differing from that stated in this Procedure, where such order has not been appealed or if appealed has not been stayed within fifteen days following the entry of the Order.

AGREED:

WYETH

By:
(signature)

Name:
(printed or typed)

Date:

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CLASS COUNSEL

By: _____
(signature)

Name: _____
(printed or typed)

Date: _____

SEVENTH AMENDMENT LIAISON
COMMITTEE

By: _____
(signature)

Name: _____
(printed or typed)

Date: _____

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